



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0032]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0331. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Labeling; Notification Procedures for Statements on Dietary Supplements--21 CFR 101.93

OMB Control Number 0910-0331--Extension

Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(r)(6)) and § 101.93 (21 CFR 101.93) of our regulations require that, no later than 30 days after the first marketing, we be notified by the manufacturer, packer, or distributor of a dietary supplement that it is marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the FD&C Act. In accordance with these requirements, submissions must include: (1) the name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) the signature of a responsible individual or the person who can certify the accuracy of the information presented, and who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

Our electronic form (Form FDA 3955) allows respondents to the information collection to electronically submit notifications to FDA via an electronic system. We are upgrading our current system (the FDA Unified Registration Listing System known as FURLS) to deploy the Food Applications Regulatory Management (FARM) system. FARM is modeled after FURLS and collects the same information, but improves our operational efficiency. A web link of the FARM system can be found here:

<https://www.fda.gov/Food/DietarySupplements/IndustryInfo/ucm485532.htm>. Firms that prefer

to submit a paper notification in a format of their own choosing still have the option to do so; however, Form FDA 3955 prompts respondents to include certain elements in their structure/function claim notification (SFCN) described in § 101.93 in a standard electronic format and helps respondents organize their SFCN to include only the information needed for our review of the claim. Note that the SFCN, whether electronic or paper, is used for all claims made pursuant to section 403(r)(6) of the FD&C Act, including nutrient deficiency claims and general well-being claims in addition to structure/function claims. The electronic form, and any optional elements prepared as attachments to the form (e.g., label), can be submitted in electronic format. Submissions of SFCNs will continue to be allowed in paper format. We use this information to evaluate whether statements made for dietary ingredients or dietary supplements are permissible under section 403(r)(6) of the FD&C Act.

In the *Federal Register* of February 7, 2019 (84 FR 2528), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Description of Respondents: Respondents to this collection of information include manufacturers, packers, or distributors of dietary supplements that bear section 403(r)(6) of the FD&C Act statements on their labels or labeling.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
101.93	3,690	1	3,690	0.75 (45 minutes)	2,767.5

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our burden estimate reflects an overall increase of 1,117.5 hours (from 1,650 hours) and a corresponding increase of 1,490 responses (from 2,200 responses). We attribute this adjustment to an increase in the average number of notification submissions we received over the

preceding 12 months, which we expect will continue over the next 3 years. We believe gathering information to satisfy the notification requirements of section 403(r)(6) of the FD&C Act by submitting information regarding section 403(r)(6) of the FD&C Act statements on labels or in labeling of dietary supplements imposes minimal burden on respondents. We expect the information needed is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. We believe also that submission via the FARM system will facilitate reporting for respondents. We estimate that, each year, approximately 3,690 firms will submit the information required by section 403(r)(6) of the FD&C Act. Assuming firms require 0.75 hour to gather the information needed and prepare a communication, we calculate a total of 2,767.5 hours (3,690 total annual responses \times 0.75 hour).

Dated: May 28, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-11419 Filed: 5/30/2019 8:45 am; Publication Date: 5/31/2019]